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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
VOGEL, NANCY TREPTOW	
ART UNIT	**PAPER NUMBER**
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,635	KENYON ET AL.	
	Examiner	Art Unit	
	NANCY VOGEL	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,10,11,14-23,26,27,31-33,46,50 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 10, 11, 14-23, 26, 27, 31-33, 46, 50, 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/22/09 has been entered.

Claims 1-3, 6, 10, 11, 14-23, 31-33, 46, 50, 53 are pending in the case.

Any rejection of record in the previous action not addressed in this office action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6, 10, 11, 14-23, 26, 27, 31-33, 46, 50, 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: *"specification* shall contain a written description of the invention...]emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d *1555,* 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d *1565,* 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claims 1, 21, 46 recite a polypeptide has 95% identity to the Ibp-7 polypeptide in Table 3 and 6. The claimed genus of polypeptide encompasses a large number of polypeptides with various sizes and function because the polypeptides need only share 95% identity to the Ibp-7 protein and be encoded by a nucleic acid that is upregulated when daf-16 activity is

inhibited, and is downregulated when daf-2 activity is inhibited, and may have be a polypeptide of different function than lbp-7 (encoded by T22G5.2). The lbp-7 is listed in the Table 3, 6 and 8 of the specification for genes with aging function in different genetic background (Table 3 and 8) and a list of class 2 genes (Table 6) with aging function. The specification discloses that lbp-7 is differently regulated in daf2 or dafl 6 genetic background in C. elegans, being upregulated when dafl 6 activity is inhibited and is downregulated when daf2 activity is inhibited, and asserting that lbp-7 is a candidate gene for shortened life span. However, while the specification also discloses other genes in this category, the specification fails to disclose whether polypeptide sharing sequence homology with lbp-7 up to 95% is also differentially regulated in same manner as lbp-7 in C. elegans. While the skilled artisan is able to identify the genus of polypeptides having 95% homology with lbp-7, whether these polypeptides sharing 95% homology with lbp-7 would be differentially regulated in the same manner as lbp-7 in C. elegan is unpredictable because neither prior art nor the specification teaches such variants, and thus the structural functional relationship is missing. A search of the prior art reveals only limited information regarding lbp-7, which teaches that T22G5.2 is expressed at a lower level in daf-/- mutants. However, this does not remedy the deficiency of the instant specification for fail to provide sufficient description for the claimed genus of polypeptide that are used to identify a compound that modulates aging. Since the specification only discloses the lbp-7 polypeptide

encoded by the sequence of T22G5.2 is a candidate gene for shortened lifespan in C. elegans without teaching what structure/sequence of the T22G5.2 is important for such

function, or which activity of lbp-7 is responsible for such function and its corresponding structure, it would have been hard for a skilled artisan to envision the structure of the lbp-7 which is responsible for the life shortening function. As such, the method of using the claimed genus of polypeptides to identify compound that modulates aging lack adequate description because the specification does not provide sufficient description of this genus of polypeptides. Thus, the specification thus fails to describe the claimed genus by a representative number of species by their complete structure, nor other identifying characteristics to demonstrate Applicants had possession of the claimed invention at the time the application was filed. Therefore, the written description requirement is maintained.

In response to this rejection, Applicants state only that due to the amendment to the claims, the rejection is overcome. However, the amendment to the claims merely changes the claims to recite that the encompassed polypeptide has at least 95% identity to the lbp-7 protein in Tables 3 and 5 and that the lbp-7 polypeptide is encoded by a nucleic acid that is expressed in C. elegans and is upregulated when daf-16 activity is inhibited and is downregulated when daf-2 activity is inhibited. Therefore, the same reasons for the rejection as were presented in the response of 1/22/09 are maintained, since there still is a lack of correlation between the structure of the polypeptide and the alleged function of the polypeptide. There are still encompassed a great number of polypeptides, and it is unclear which part or domain of lbp-7 is responsible for fatty acid binding function, and which part or domain or amino acids are necessary for regulating

aging in C. elegans, and whether these domains are the same or different. While not every species needs to be described to satisfy the written description requirement, the specification still needs to provide adequate description of characteristics which can make a skilled artisan be able to identify the structure of the claimed genus of nucleic acids or polypeptides based on the alleged function. Without such information (no description in specification and not known in the art), whether altering any amino acid sequence of lbp-7 or part of the sequence from T22G5.2 that encodes any part of the lbp-7 would still retain both alleged function of the lbp-7 is unpredictable. Thus, the claimed function would not be tied to a unifying structure of the claimed genus of nucleic acids and polypeptides encoded by said nucleic acids. Since the instant claims are drawn to a method of identifying a compound that modulates aging using the claimed genus of nucleic acids and encoded by said nucleic acids, but not nucleic acids or polypeptides themselves, the function of the claimed genus of nucleic acids and polypeptides encoded by said nucleic acids is required in order to practice the claimed method. Applicants are reminded again that it is not sufficient to have possession of the nucleic acid sequences and polypeptide sequences at the time of filing. The structural and functional relationship between the sequences and alleged function is important to satisfy the written description requirement for instant claims because the function of such claimed genus of sequences is required to practice the claimed invention. As discussed above, the specification needs to provide description of either a representative number of species by their complete structure or other relevant identifying characteristics. For reasons given in the previous office action and above,

the specification fails to do both. As such, the claimed method lacks adequate description.

Claims 1-3, 6, 10, 11, 14-23, 26, 27, 31-33, 46, 50, 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is re-written to address the amendment.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to
make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The nature of the invention

The nature of the invention is a method for identifying a compound that modulate aging by contacting a test compound with a polypeptide that is a C. elegans lipid binding protein-7, wherein the lbp-7 has 95% identity to lbp-7 in Tables 3 and 6, and determine

the effect of the compound upon the activity or expression of said lbp-7, wherein a difference between the control without the test compound indicates the compound modulates aging. The dependent claims are further drawn to such a method wherein the activity of the lbp-7 is measured by transcription of the nucleic acid, fatty acid binding to the polypeptide, expression of an age associated gene, duration of the lifespan, wherein the host cell is a C. elegans cell, a mouse cell, a rat cell, a human, a whole organism of C. elegans, mouse, rat or human.

The breadth of the claim

The breadth of the claim is very broad. The claimed scope encompasses identifying a compound of any nature by contacting it with a polypeptide having at least 95% identity to lbp-7 and determine any type of the functional effect upon the polypeptide. The claimed scope also encompasses identify a compound that is able to modulate aging in any organism.

The teaching of the specification

The teaching of the specification regarding how to identify a compound that modules aging by contacting it to the claimed polypeptide is rather limited. The specification teaches using microarray and other methods to identify genes that changes expression in daf2 or dafl 6 mutants which prolongs life in C. elegan. The specification discloses class 1 and class2 genes which affect the lifespan of C. elegan differently. However, the specification fails to teach what the effect T22G5.2 has in this process is. Although T22G5.2 is listed in Table 3, indicating it is a class 2 gene, whose transcription is decreased in daf2 minus genetic background, but is increased in daf2-dafl 6- double

mutant in C. elegans, the specification does not provide an explanation of what roles lbp-7 listed in Table 3 has in the aging process. Even the prior art teaches that lbp-7 is a fatty acid binding polypeptide, the specification does not disclose how the fatty acid binding activity of said polypeptide or its variants having 95% homology would relate to the age modulating function of said polypeptides. Moreover, while it appears that lbp-7 is a downstream target of daf and/or dafl 6, it is unclear whether changing in the expression of said lbp-7 without daf2 and or dafl 6 genetic background would result in a difference in aging in C. elegans. In other words, the specification fails to explain how to identify a compound that can modulate aging simply by contacting it to the polypeptide encoded by T22G5.2, lbp-7 or sequence homologous to lbp-7 or a cell that expresses lbp-7. The specification fails to establish a nexus between the functional effect such as fatty acid binding or increased transcription of T22G5.2 to the aging process in C. elegan. Moreover, the specification also fails to teach whether the observed differential regulation of the expression of T22G5.2 in C. elegans is also observed or may be used to predict the same effect in other types of cells or whole organism drastically more complicated than C. elegans, such as mammals even including human beings. Based on the very

limited information provided in the instant specification, whether the claimed method may be practiced in any of the cells or organism as claimed is unpredictable. As such, one of skilled in the art would have to rely on the information available in art to practice the method as claimed.

The state of art and level of unpredictability in the art

The state of art at the time of filing is silent with regard to the claimed method. In fact, very little is known about the function of lbp-7, encoded by T22G5.2, with regard to its function in aging. Murphy et al. teach that lbp-7 is a downstream molecule of dafl 6, whose expression is down-regulated in daf2- C. elegans, whose life is extended than the wild type. However, Murphy et al. do not provide further teaching on how to identify a compound that modulate aging by contacting said compound with a polypeptide encoded by T22G5.2, a nucleic acid having homology with T22G5.2, or whether lbp-7 modulates aging in any other cells or organisms. The prior art also fails to teach any polypeptide encoded by a nucleic acid hybridizable to the T22G5.2 which is related to aging. As discussed above, although C. elegans lbp-7 is differentially regulated in daf2- and daf2-dafl 6- genetic background whereas the organism appears to have different lifespan, the specification at most teaches that lbp-7 may be downstream target of daf2 and dafl 6, wherein its direct involvement in aging process is still unpredictable. Moreover, it is unclear what the nexus between its fatty acid binding activity to the alleged aging modulating activity is for this polypeptide. The prior art also fails to indicate how T22G5.2 is related to aging in cells or organisms other than C. elegan. As such, the nexus between those polypeptide and aging is missing. Consequently, whether the polypeptides, cell or organism expressing said polypeptides may be used to identify a test compound of any nature that can modulate aging is unpredictable. In view of very limited teaching from the prior art, it

does not remedy for the lack of guidance of the specification to enable a skilled artisan to practice the method as claimed. Since the prior art does not teach how to identify a

compound that modulates aging by simply contact it with a polypeptide encoded by T22G5.2, a cell or organism expresses said lbp-7, and the specification does not teach how to practice the method as claimed, one of skilled in the art would have to engage in undue experimentation to practice the method as claimed. Therefore, the claimed method is not enabled by the instant specification.

In response to this rejection, Applicants argue that due to the amendment to the claims, the rejection should be withdrawn. However, for the reasons set forth above, the rejection is maintained

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

NV
8/3/09